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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,980	09/30/2003	Yaron Ilan	Enz-64 (CIP)	9089

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ENZO BIOCHEM, INC.
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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,980	IIAN ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/7/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6, 11, 43-45, 47-52, 54, 59-60, 75-76, 97, 109, 120, 125-126, 151, 157, 161-169, 184 and 191* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-118,120-123,125,126,129-151,154-169,171-177,183-185,187,189-191,197,198 and 200-202.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-5,7-10,12-42,46,53,55-58,61-74,77-96,98-108,110-118,121-123,129-150,154-156,158-160,171-177,183,185,187,189,190,197,198 and 200-202.

DETAILED ACTION

This action is responsive to communication filed 7/7/2009. The status of the claims is as follows: claims 1, 6, 11, 43-45, 47-52, 54, 59-60, 75-76, 97, 109, 120, 125-126, 151, 157, 161-169, 184 and 191 are under current examination, claims 2-5, 7-10, 12-42, 46, 53, 55-58, 61-74, 77-96, 98-108, 110-118, 121-123, 129-150, 154-156, 158-160, 171-177, 183, 185, 187, 189-190, 197-198 and 200-202 are withdrawn and claims 119, 124, 127, 128, 152, 153, 170, 178-182, 186, 188, 192-196, 199 and 203-205 are cancelled. The elected species are monosaccharide ceramide and colitis. Note that no additional species were searched given the rejections below.

Any rejection or objection not reiterated herein has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/7/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. This claim recites "wherein the result comprises changes in cytokine responses" of claim 1. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Appropriate correction is required.

Claims 49, 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 49 recites "wherein the result comprises changes in cytokine responses" of claim 43. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Dependent claims fall herein. Appropriate correction is required.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "wherein the result further comprises changes in the Th1/Th2 balance" of claim 43. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Appropriate correction is required.

Claims 161, 165 and 167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "wherein the result comprises changes in cytokine responses" of claim 44. It is not clear whether the result results from said administration or results from said

pathogenesis of the disease. Dependent claims fall herein. Appropriate correction is required.

Claim 163 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "wherein the result further comprises changes in the Th1/Th2 balance" of claim 44. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Appropriate correction is required.

Claims 162, 166 and 168 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "wherein the result comprises changes in cytokine responses" of claim 45. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Dependent claims fall herein. Appropriate correction is required.

Claim 164 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites "wherein the result further comprises changes in the Th1/Th2 balance" of claim 45. It is not clear whether the result results from said administration or results from said pathogenesis of the disease. Appropriate correction is required.

Claim 191 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 191 recites the limitation "manipulation" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, 11, 43-45, 47-52, 59-60, 97, 120, 125, 151, 157, 161-169 and 184 rejected under 35 U.S.C. 102(b) as being anticipated by Marinier (US Patent 5747463, published May 5, 1998).

Marinier discloses a treatment of a disease in a mammalian subject comprising administering an effective amount of a mammalian intermediary metabolite comprising a glycolipid, wherein the pathogenesis of the disease is derived from an inflammatory immune response (i.e. elected species, colitis); see abstract, Formula I and col. 2, lines 47+. Note that Formula I meets the claim limitations of a mammalian intermediary metabolite including glycolipid, monosaccharide ceramide and galactosylceramide (see instant claims, including claim 1, 125 and 169) and a therapeutically effective amount is described (col. 3, lines 37+). The authors describe a step of administration including oral, intravenous, intramuscular etc. (see col. 33, lines 35+ and instant claim 151).

It is noted that the limitations of many instant claims, including claims 47-52, are not *active steps* in the claims, but only the mechanisms of action which occur by the series of active steps in the claims. The prior art discloses the same active steps of the instant claims, including administrating of an intermediary metabolite, thus, the same mechanisms of action must occur because the composition/method use and its properties are inseparable. See also claims 43 (lines 5+), 44 (lines 5+), 45 (lines 5+), 59 e), 60 (lines 5+), 97 e) and 161-168.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 75, 109 and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marinier (US Patent 5747463, published May 5, 1998) as applied

to claims 1, 6, 11, 43-45, 47-52, 59-60, 97, 120, 125, 151, 157, 161-169 and 184 above, and further in view of Das (US Patent 5869048, published February 9, 1999).

Marinier discloses a method of administering a mammalian intermediary metabolite to a subject for the treatment of colitis (see above).

Marinier does not disclose further administering antigen associated with colitis.

Das describes a method of vaccinating a human against ulcerative colitis which comprises administering a therapeutically effective amount of a colonic antigen associated with ulcerative colitis obtained from a human (see Abstract and col. 3, lines 16+).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further administer a colonic antigen in the method taught by Marinier. One of ordinary skill in the art at the time the invention was made would have been motivated to do so for the advantage of vaccinating a subject against ulcerative colitis as taught by Das. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success given the underlying techniques are widely known and commonly used in the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 54, 76 and 191 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marinier (US Patent 5747463, published May 5, 1998) as applied to claims 1, 6, 11, 43-45, 47-52, 59-60, 97, 120, 125, 151, 157, 161-169 and 184

above, and further in view of Collins (PGPUB 20020141977, published Oct. 3, 2002) and Liotta (US Patent 6610835, published Aug. 26, 2003).

Marinier discloses a method of administering a mammalian intermediary metabolite to a subject for the treatment of colitis (see above).

Marinier does not disclose further administering a dendritic cell or using a subject that has been without food for a minimum of 12 hours prior to administation.

Collins describes a general method of immunotherapy based on antigen presenting cells including dendritic cells for the prevention and/or treatment of various diseases such as inflammatory diseases (see Title and Abstract).

Liotta discloses that sphinogolipids are found in a number of foods, including wheat flour, potato and beans (col. 9, lines 24+).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further administer a dendritic cell to a food deprived animal using the method taught by Marinier. One of ordinary skill in the art at the time the invention was made would have been motivated to use dendritic cells for the advantage of providing a known method of immunotherapy to subject as taught by Collins. One of ordinary skill in the art at the time the invention was made would have been motivated to use animals that are food deprived in order to better control the amount of intermediary metabolites in a subject and to regulate intermediary metabolite-induced effects. Note that one of ordinary skill in the art at the time the invention was made would have been motivated to alter the duration (hours) of food deprivation in order to optimize the effects of the administered metabolites. One of ordinary skill in the art at

the time the invention was made would have had a reasonable expectation of success given the underlying techniques are widely known and commonly used in the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 11, 43-45, 47-52, 54, 59-60, 75-76, 97, 109, 120, 125-126, 151, 157, 161-169, 184 and 191 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9-15 of copending Application No. 11/378, 941. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed towards administering the same compounds.

In response to the rejection(s), Applicant requests that the rejection is held in abeyance (Remarks, p. 45). This has been noted, however, until the rejection is properly addressed, it is maintained on the record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646